

PSJ3

Exhibit 54B

1 cell patients seem to have to sign contracts but
2 cancer patients at elite institutions don't.

3 So I have a great concern about the
4 discrimination that goes on about contracts that
5 needs to be sorted out. So, that's one example.

6 I think that we are not saying everyone
7 should have a contract but only some people
8 should have a contract. And I have a concern
9 that that could be misused for patients.

10 Q. When you say some people -- and I
11 appreciate your concern for the poorer people and
12 discrimination. Where you say some people have
13 to have it, I am trying to understand how that
14 fits in the context of your concern?

15 A. That we are identifying some groups at
16 greater risk or at greater chances of misusing
17 drugs. And we already know in this country that
18 minorities are discriminated, they are
19 inadequately treated for their pain. We know
20 that they have less access to prescriptions,
21 filling their prescriptions in New York
22 pharmacies. That's been published.

23 We have evidence that their pain is
24 untreated in a variety of settings. And I have a
25 concern that these contracts might be used to

1 limit access to these treatments for certain
2 populations of patients. So, I have a concern
3 about that.

4 Q. I see. But this contract that Tennant &
5 Olman are proposing I don't think is limited to a
6 white or black issue, poor or rich.

7 A. No, I am broadly responding to the
8 construct of do I agree with contracts or not
9 contracts. So you are asking me do I agree with
10 what they did, I am describing what they did.
11 And I describe things that people say they say
12 simply to be fair, to have that in the literature
13 as a discussion. And that was the purpose of
14 placing it here.

15 Q. I understand but I am trying to
16 understand the answer you just gave in the
17 context of how this would discriminate somehow.
18 Are you saying that the people that would
19 typically sign the contracts would fit into the
20 category of the poorer class or --

21 A. That institutions would demand that
22 certain people sign contracts and others would
23 not.

24 Q. So, they wouldn't use them the way they
25 are supposed to be used?

1 A. They might disuse -- there may be
2 significant discriminatory practice associated
3 with the use of contracts which might limit
4 access to patients being adequately treated for
5 their pain.

6 Q. The next sentence talks about, it says,
7 they suggest -- is that referring to Tennant &
8 Olman?

9 A. That is correct.

10 Q. The consent discussion includes risk of
11 using alcohol, other drugs while taking opioids,
12 the likelihood that a newborn will be physically
13 dependent on opioids if these drugs are taken by
14 a female patient during pregnancy and the
15 possibility which the current data cannot refute
16 absolutely that the psychological dependence to
17 opioids can occur and may last a lifetime. Is
18 that still true today?

19 A. Yes.

20 Q. Now, when you talk about psychological
21 dependence, you are talking about addiction; is
22 that correct?

23 A. I am quoting that but I am talking about
24 addiction.

25 Q. You understand that the psychological

1 dependence to your way of thinking means
2 addiction; is that right?

3 A. That is correct.

4 Q. And, do you agree with the statement
5 that if somebody has psychological dependence or
6 addiction that it may last a lifetime?

7 A. It's not my opinion. That's been an
8 opinion that has been put forth by a variety of
9 experts in addiction.

10 Q. And, you agree with that?

11 A. They are the experts and that's what
12 they say.

13 Q. Well, you feel you are not qualified to
14 comment on that?

15 A. No, I mean, I agree with it.

16 Q. You agree that addiction lasts a
17 lifetime?

18 A. Yes.

19 Q. Addiction is something -- if you have
20 addiction, if a patient has addiction, is it
21 something that you have to treat?

22 A. No.

23 Q. Is it something that you have to tell
24 the patient something about the condition so they
25 can monitor it or --

1 A. I guess I think -- may I ask a
2 question? I don't think I understand your
3 question.

4 Q. You can ask that question. That's
5 actually more of a statement than a question but
6 --

7 A. Sorry about that. Could you repeat the
8 question?

9 Q. Sure. If a person has addiction to
10 opioids, do you agree that that condition lasts
11 throughout the rest of their life?

12 A. Do you mean if a patient actually is
13 addicted to opioids at that time?

14 Q. Yes.

15 A. Or has a history of addiction?

16 Q. Either one.

17 A. If the patient is actually addicted at a
18 point in time, then that patient needs
19 treatment. That patient needs to be tapered off
20 their drugs and may need a treatment program.

21 Q. And, the treatment program can include
22 what?

23 A. There are a variety of treatment
24 programs. There are abstinence programs and
25 there are drug free communities. There are

1 methadone maintenance programs. There is
2 buprenorphine treatment. There are a variety of
3 treatments for someone who has -- is actively
4 abusing opioids and needs to be treated for that.

5 Q. And, again, you have used the word
6 abusing?

7 A. Is actively abusing and is considered on
8 a DSM four diagnosis to be substance dependent
9 and addicted and meets all the criteria of that.

10 Q. Do you utilize the DSM four criteria
11 when you would consider somebody to be addicted?

12 A. There are a variety of criteria that one
13 might use but that's one of them.

14 Q. Is that in your opinion an acceptable
15 criteria, DSM four?

16 A. In identifying addicts, yes. But it's a
17 very complicated one to use in patients who have
18 taken opioids in the setting of chronic pain.

19 Q. In terms of assessing a patient who has,
20 potentially, addiction as defined by DSM four,
21 would you agree -- you just used the word
22 complicated, that that can involve a pretty
23 thorough evaluation of the patient in order to
24 make that diagnosis?

25 A. It involves a detailed history taking

1 from the patient.

2 Q. And, would you think that -- have you
3 ever done that yourself?

4 A. Um-uh.

5 Q. Have you ever diagnosed someone with
6 addiction to opioid medication?

7 A. Yeah.

8 Q. And, have you used the DSM four criteria
9 to make that diagnosis?

10 A. Yeah, um-uh.

11 Q. And, you feel you are qualified to do
12 that; correct?

13 A. That's right, um-uh.

14 Q. And, would you agree that psychologists
15 and psychiatrists might be someone who would be
16 qualified to make that type of determination?

17 A. Yes, um-uh.

18 Q. Now, on the next paragraph here, this is
19 like towards the middle of the page, maybe going
20 towards the bottom, it says here in a sentence --
21 and I will let you find it before I ask a
22 question about it. If dose escalation continues
23 to rise over several weeks or if a rapid rise in
24 the absence of a documented change in disease
25 occurs, it is recommended that the patient be

1 hospitalized in order to facilitate evaluation of
2 the medical requirement -- medication requirement
3 and if possible return to base line dose?

4 A. Um-uh.

5 Q. And, was that something that you agreed
6 with in 1985?

7 A. I did. I agree with that.

8 Q. Is that still true today?

9 A. It would not be possible to admit the
10 patient to a hospital any longer. The way that
11 health care financing has changed, you would not
12 be able to admit the patient to the hospital.
13 That would not be possible.

14 Q. Well, would you agree that in lieu of
15 admitting the patient to the hospital, the
16 patient should be reevaluated?

17 A. Yes, and what the sentence is really
18 suggesting is the reevaluation.

19 Q. And, possible return to base line dose?

20 A. Correct.

21 Q. Is the import of this that you just
22 don't escalate the dosage of the drug without
23 having a good reason to do it?

24 A. That is correct.

25 Q. And, that's still true today; right?

1 A. That is correct.

2 Q. It says, the next sentence, most
3 patients in the surveys of opioid maintenance
4 therapy published thus far have required modest
5 doses of drugs. The need for relatively high
6 doses must be especially scrutinized to insure
7 that the drug is appropriately used and
8 specifically the pain is the symptom being
9 treated. Is that still true today?

10 A. Yes, it is.

11 Q. And, when you say that the pain is a
12 symptom being treated, are you referring back to
13 the possibility that there might be other factors
14 involved in the patient's perception of pain?

15 A. Again, I would not say in the perception
16 of pain but in their pain behaviors.

17 Q. Okay; I apologize but I am having
18 trouble understanding that. If a patient comes
19 into the office and says -- doctor says, do you
20 hurt? And the patient says yes. And the doctor
21 says, do you hurt on a scale of one to ten, one
22 or ten, and the patient says ten. Is it -- in
23 this sentence, are you saying that there is a
24 concern that maybe when the patient says ten,
25 there might be other things besides a

1 physiological reason for the pain that the
2 patient says ten instead of three?

3 A. Yes, I agree with that.

4 Q. And, those factors might be social,
5 economic, the things we talked about before; is
6 that true?

7 A. They may be psychological, they may be
8 social.

9 Q. Or economic; true?

10 A. Again, the economic, they could be
11 economic but I continue to argue that economic
12 indirectly impacts on psychological and social.
13 And so I don't have -- I don't want to make a
14 direct line of economic to --

15 Q. It's an indirect relationship, that is,
16 the person -- if the person is in bankruptcy and
17 they might be -- I am sorry, did you finish your
18 answer?

19 A. Go ahead.

20 MR. HOFFMANN: I was trying to stop her
21 from answering before you finished your
22 question. That's why I put up my hand.

23 MR. COLANTONIO: So, you were trying to
24 tell her not to continue the answer, that's a
25 change.

1 MR. HOFFMANN: No, I was trying to tell
2 her to let you finish your question.

3 MR. COLANTONIO: All right; thanks.

4 THE WITNESS: Sorry.

5 BY MR. COLANTONIO:

6 Q. So, the inferential relationship is if a
7 person has bankruptcy or they have bad financial
8 condition, they might be depressed. It might
9 effect their psyche and therefore they might say
10 I hurt ten instead of three as a factor; is that
11 fair?

12 A. I agree with what you just said.

13 Q. The next sentence says, evidence of
14 inappropriate use such as opioid intake to treat
15 the depression or anxiety of such abuse behaviors
16 as diversion or hoarding should be pursued and
17 managed firmly. If control cannot be maintained,
18 opiate therapy should be discontinued. That's
19 true today; correct?

20 A. Yes, although, again, there is an
21 evolving science now to recognize that opioid
22 therapy may not be able to be discontinued
23 because the patient is in severe pain and one has
24 to provide them with better pain relief. So then
25 the ethical responsibility of the physician to

1 take care of a patient, let's say, with, you
2 know, advanced AIDS and severe chronic pain in
3 the setting of drug abuse and so I think we have
4 a more sophisticated and more organized approach
5 to caring for patients that may end up in that
6 situation.

7 Q. These guidelines we have been talking
8 about, these concepts we have been talking about,
9 you agree they apply not just to chronic pain but
10 also to treatment of acute pain as well; right?

11 A. Well, I don't think I would want to say
12 -- there is sort of a general conceptualization
13 that you evaluate the patient, that you pay
14 attention to all these issues, that pain can have
15 many factors. But I think the distinction is
16 patients with acute pain usually have an
17 immediate cause for their pain, usually have a --
18 respond typically to the agents that are
19 available and will taper off their drug. So they
20 are different.

21 Q. So, they are different?

22 A. They are quite different. They are not
23 taking the drug for this long period of time.

24 Q. They are different but the principles we
25 have just gone through would still apply. For

1 example, you need to watch dose escalation, there
2 should be a reason for it. You need to have
3 fully informed consent and other things we have
4 talked about would also apply to opioid treatment
5 in an acute pain situation; right?

6 A. Well, I am not -- if patients are going
7 to take an analgesic for an acute pain, a post
8 operative pain, I am not sure that as general
9 practice we fully inform them of every aspect of
10 treatment since they are going to be on it for
11 three days or five days and discontinue their
12 drug. So I guess I am making a little bit of a
13 distinction in the management.

14 And acute post-operative pain would be
15 the best and most common model in this country.
16 The patients are fully informed that they are
17 going to receive a drug, it may be an opiate,
18 those are the side effects. Those are pieces of
19 information that they are provided with.

20 Q. Are you saying the informed consent
21 given for patients on opioids more than three
22 months should be different than that for acute
23 situations?

24 A. Well, that's why we are talking about
25 these guidelines for chronic pain.

1 Q. Well --

2 A. But, the general framework and
3 principles are very similar.

4 Q. I think that was my point.

5 A. Okay.

6 Q. That the general framework and
7 principles are similar. There may be some slight
8 nuances that might apply to a chronic situation
9 versus acute, but you still want to give the
10 acute treatment informed consent; right? Or am I
11 wrong?

12 A. Well, if by informed consent is that you
13 want the patient to be knowledgeable about the
14 treatment that they are receiving, then yes.

15 Q. Isn't that the purpose of informed
16 consent?

17 A. Yes.

18 Q. And, in acute situations, you want to
19 make sure you are treating a condition that can
20 be described by physiological reasons, not social
21 or economic or psychological reasons, correct?

22 A. That would be correct.

23 Q. I mean, those all apply across the
24 board, whether acute or chronic?

25 A. Yes, but the risk of a patient taking a

1 drug for three to five days is different
2 potentially than it is for taking it for 20
3 months or so.

4 Q. How so?

5 A. Because of the fact that the patient's
6 pain will be diminishing rather than increasing
7 and their dose requirements will be diminishing.
8 So it is a different pattern of how they would
9 take it.

10 Q. How about in terms of the potential for
11 abuse and addiction, the risks of those?

12 A. Again, it is related to the duration of
13 taking the drug. It is related to the dose.
14 It's related to the setting and then of all the
15 other factors that we talked about.

16 Q. So, you agree that addiction -- there is
17 a relationship between dose and the risk of
18 addiction?

19 A. Yes.

20 Q. You agree that there is a relationship
21 between a person's social economic factors and
22 potential for addiction?

23 A. That's described in the literature.

24 Q. You agree with that?

25 A. Sure.

1 Q. And, you agree that there is a
2 relationship between the length of time on opiate
3 medication and the potential for addiction?

4 A. Yes.

5 Q. Would you agree then that the rates of
6 expected addiction for people in groups would be
7 different based upon their social, economic,
8 psychological factors, the dosing and the length
9 of time that they are taking the drug?

10 A. I think that the development of
11 addiction is individual. So I don't want to
12 limit it to groups. It's an individual aspect.
13 It depends on who the patient is.

14 Q. I suppose we could say that about -- I
15 am sorry.

16 MR. HOFFMANN: Go ahead and finish your
17 answer.

18 MR. COLANTONIO: That was mine.

19 THE WITNESS: It depends on who the
20 patient is. This is probably the most
21 important factor. And so -- and I would
22 argue it depends much more on who the patient
23 is than the drug.

24 BY MR. COLANTONIO:

25 Q. But, who the patient is includes social

1 setting, economic setting, psychological setting,
2 those kinds of things; true?

3 A. Yes. Yes, it does.

4 Q. And, those all play a role --

5 A. Yes.

6 Q. I am sorry, you have to let me finish my
7 question. Those all play a role to your way of
8 thinking in the expected rate of addiction?

9 A. Yes.

10 Q. And, when you say it's individual in
11 terms of expected rate of addiction to opioid
12 medication, I mean, that's true for pretty much
13 every disease and medication. I mean, how that
14 effects a person is individual because each
15 person probably isn't exactly alike chemically
16 and makeup wise but that's true generally across
17 the board for medicine; right?

18 A. Well, it may well be different and I
19 think we have a lot of reasons to think it may be
20 different for this concept of addiction because
21 we have this extraordinary experience of treating
22 large numbers of patients with opioids for long
23 periods of time who don't become addicted.

24 Q. Okay.

25 A. And, so the use of opioids in the

1 setting of treating patients with chronic pain
2 seems to be different than the misuse of opioids
3 for recreational purposes in an addict
4 population. So, we -- and that begins to say
5 that there must be very powerful individual
6 differences among these groups and these
7 individuals within these groups that allow
8 someone to take opioids for months on end, to
9 have successful treatment of their pain and then
10 to be tapered off their drug and that's the
11 clinical experience.

12 Q. The clinical experience you are
13 referring to is in cancer pain patients?

14 A. And in chronic non-malignant pain
15 patients.

16 Q. And the chronic non-malignant pain
17 patients you are talking about, the experience,
18 the documented experience, that is what?

19 A. In groups of patients who develop an
20 acute herpes zoster that go on to develop post
21 herpetic neuralgia and then improve, in patients
22 who have post surgical pain syndromes that are
23 not related to their cancer but occur in the
24 cancer setting that go on for six months or nine
25 months and then improve and they taper off their

1 drug.

2 Q. I am talking about -- I am sorry, are
3 you finished?

4 MR. HOFFMANN: Go ahead and finish your
5 answer.

6 THE WITNESS: I am talking about
7 patients who have a variety of surgical
8 procedures on their knee or hip or have
9 traumatic pain who take opioid analgesics
10 during their rehabilitation and then recovery
11 and then go off their drugs.

12 BY MR. COLANTONIO:

13 Q. And, what I would like -- can you define
14 for me the published studies you are talking
15 about that embody that?

16 A. Of those patients, those I am speaking
17 of from my own clinical experience.

18 Q. I understand that. What I am trying to
19 ask you is where could I look at, what body of
20 published literature can I look to to find this,
21 any published experience besides your clinical
22 experience?

23 A. Right.

24 Q. If you can define that for me?

25 A. Yeah, I think we published a paper on

1 the types of patients that we saw in our pain
2 clinic. And we defined them in like three
3 categories, a group of patients who escalated
4 their drugs, there are a group that remained
5 stable and there was a group that decreased their
6 drugs. So that would be one population that I
7 could identify.

8 Q. I am sorry, where was that published?

9 A. I need to look at my --

10 MR. HOFFMANN: Go ahead.

11 MR. COLANTONIO: Sure.

12 THE WITNESS: And, it would be early on.
13 It's number 23 on my bibliography. It's
14 Canner Foley, patterns of narcotic drug use
15 in a cancer pain clinic.

16 BY MR. COLANTONIO:

17 Q. And that was published in what year?

18 A. It was published in 1981.

19 Q. So, that would have been published at
20 the time you published this article that we are
21 looking at?

22 A. No, this article was 1985.

23 Q. I thought you said 1981?

24 A. I said 1981 and this article is 1985.

25 Q. That's my point. The article that you

1 referred to in your bibliography just now was
2 already published at the time you published this
3 article in 1985?

4 A. That is correct.

5 Q. True?

6 A. Yes.

7 Q. Any others?

8 A. I think I really would need to think
9 about that for you.

10 Q. There are none others that you can think
11 of right now if I was to ask you for --

12 A. Other published studies of that
13 particular point?

14 Q. Yes.

15 A. No, not that I can think of at the
16 moment.

17 Q. In your -- on page 184 at the bottom
18 here, it is like the second to the last
19 sentence --

20 A. Okay.

21 Q. You say, given the paucity of data,
22 however, this course must be pursued cautiously?

23 A. Yes.

24 Q. I would like to ask you what you meant
25 by the paucity of data, what paucity of data are

1 you referring to?

2 A. Well, let me read what I said in this.

3 Q. Sure.

4 A. Okay, the paucity of data that we were
5 referring to was the limited studies of patients
6 with chronic non-malignant pain who had been
7 treated with opioids in the literature, the
8 published studies.

9 Q. In terms of their --

10 A. The experience of clinicians with it.
11 So we cited the article by Tennant. We cited an
12 article by Taub and we researched the literature
13 to find other examples. And so by paucity, we
14 were concerned about the paucity of patients.
15 So, Taub was an example.

16 Q. I think you also cited --

17 A. Sternbacks, Taub, Tennant.

18 Q. You cited also --

19 A. Turner, so those are people that had
20 published.

21 Q. You cited Porter & Jek, footnote 38, do
22 you see that?

23 A. Yes.

24 Q. And, you cited that as one of the I
25 guess pieces of data out there?

1 A. Right.

2 Q. But, even in citing that and some
3 others, you agreed at the time that you wrote
4 this, that that still constituted a paucity of
5 data at that time --

6 A. Yes.

7 Q. -- on these issues; is that correct?

8 A. Yes.

9 Q. Now, it says here in the next sentence,
10 long term prospective studies of pain patients on
11 opioid maintenance therapy are needed. And were
12 you suggesting that the long term studies were
13 needed to correct the paucity of data that you
14 were referring to in the previous sentence?

15 A. Well, they were needed for many
16 different reasons, not just to correct paucity of
17 data. They were needed to help us understand the
18 issues.

19 Q. Is that one of the reasons?

20 A. Yes.

21 Q. And, it says here these will better
22 assess the efficacy and risks of the treatment
23 itself and may provide insight into the salient
24 features which predispose to and perpetuate drug
25 abuse?

1 A. That is correct.

2 Q. And, when you use the word drug abuse
3 there, does that include sort of as a subset of
4 that, drug addiction?

5 A. It would, yeah.

6 Q. Do you believe that the terms addiction
7 and substance dependence are synonymous?

8 A. The substance dependence is the language
9 used in the DSM four TR and it is used to
10 describe addiction. So for that group, substance
11 dependence and addiction are used --

12 Q. And, you have indicated --

13 A. -- interchangeably.

14 Q. I am sorry, are you finished?

15 A. They are used interchangeably.

16 Q. And, I think you have indicated you have
17 used the DSM four in your practice before --

18 A. That's correct.

19 Q. -- in terms of diagnosing addiction;
20 true?

21 A. Correct.

22 Q. And, would you also agree that
23 psychological dependence is also synonymous with
24 substance dependence and addiction?

25 A. Well, I don't want to -- people use --

1 every time you use each of these words, you have
2 to define it. And so, therefore, I don't want to
3 say that because I don't know how a person is
4 using it. Some person may use it one way and
5 some person may use it another way.

6 So every time when someone identifies
7 and uses the word psychological dependence, I
8 want them to tell me what they mean. When they
9 say addiction, I want them to tell me what they
10 mean, and when they say substance dependence.

11 Sadly, it would be good in the field if
12 we all sat down and agreed on these definitions.
13 So I think I can't answer that in that kind of
14 general sense. It is the content, how is it
15 being used, what are you trying to define and
16 that's the best answer I can give you.

17 Q. Would you agree that even today there is
18 some disagreement among experts and clinicians as
19 to how each uses the terms addiction, substance
20 dependence, psychological dependence?

21 A. I think there is and that's why you have
22 to start the conversation with are we all at the
23 same place.

24 Q. While you believe that patients should
25 be individually assessed when they are treated

1 with OxyContin or opioids, don't you agree with
2 me that individual assessment is true in every
3 case when a medication is prescribed to a
4 patient?

5 A. I guess, yes, they need to be
6 individually assessed no matter when they receive
7 a medication.

8 Q. And, you believe that there are certain
9 things in the assessment, especially with opioid
10 medication, that are important including a
11 person's background -- we talked about social
12 factors, economic factors, psychological factors
13 that might play a role in the person's pain and
14 potential for addiction; true?

15 A. But, I would think that if you were
16 using anti hypertensives or anti depressants or
17 anti anxiety drugs or antibiotics, I would need
18 to know those pieces of information.

19 Q. So pretty much the kinds of things you
20 would assess in terms of looking at somebody,
21 whether you are going to prescribe them OxyContin
22 or anti -- or a hypertensive drug, you would
23 pretty much do the same kind of assessment?

24 A. Yes.

25 Q. So, you would do that for a hypertensive

1 drug, antibiotic, opioid, pretty much across the
2 board; is that true?

3 A. That is correct.

4 Q. So, while there is individual assessment
5 you believe for patients being prescribed
6 medications, the commonality in all of that is
7 that when a physician considers a prescription
8 for a patient, they have to do that assessment
9 for every medication they write; correct?

10 MR. HOFFMANN: Object to the form of the
11 question.

12 BY MR. COLANTONIO:

13 Q. Do you understand my question? In other
14 words, the assessment is common with any drug?

15 MR. HOFFMANN: I am going to object to
16 the form of that question too, but if you can
17 answer it, go ahead.

18 THE WITNESS: Well, you need to measure
19 the blood pressure if the patient is -- if
20 you are using anti hypertensives. You need
21 to measure the blood sugar if you are using
22 insulin. I mean, there are very specific
23 assessments that go with each of the drugs as
24 well that are specific. So there is a
25 general and then there is a specific. So for

1 each class of drugs, there would be a
2 specific assessment as well.

3 BY MR. COLANTONIO:

4 Q. But, it is common to all patients that
5 there is an assessment done for a drug before it
6 is prescribed?

7 A. There is an assessment made that is
8 directly influenced by that drug. So you would
9 ask a series of factors about food intake and
10 glucose intake for someone you are prescribing
11 insulin to.

12 Q. But, my question is, you agree that is
13 common to all --

14 A. I would not ask every patient about
15 their food intake if I was not prescribing
16 insulin.

17 Q. I understand that but what I am saying
18 is I know there are specific nuances to each
19 different medication because there may be
20 different conditions you are treating. My
21 question I am asking you is, the assessment
22 itself, that the physician does the assessment,
23 it is common to any medication, the fact that you
24 do an assessment?

25 A. It's not so much common to every

1 medication, it is common to the doctor patient
2 relationship and the setting in which you are
3 caring for the patient.

4 Q. All right; now, is it your belief today
5 on August 28th or something like that, 2004 --

6 MR. HOFFMANN: 27.

7 MR. COLANTONIO: Thank you, 27, 2004
8 that the use of opioid analgesics such as
9 OxyContin by physicians for the treatment of
10 patients with acute pain is inadequate?

11 THE WITNESS: Would you repeat that for
12 me?

13 BY MR. COLANTONIO:

14 Q. Sure. Is it your belief today, August
15 27, 2004, that the use of opioid analgesics like
16 OxyContin by physicians for the treatment of
17 patients with acute pain is inadequate at best?

18 MR. HOFFMANN: I am going to object to
19 the form of the question. But if you can
20 understand it, you can answer it.

21 BY MR. COLANTONIO:

22 Q. Do you understand that?

23 A. Could you say it one more time and I am
24 not trying to be difficult.

25 MR. HOFFMANN: Say it one more time.

1 THE WITNESS: But, I am just --

2 BY MR. COLANTONIO:

3 Q. It's going to be easier if I just show
4 you your expert disclosure and ask you to take a
5 look at this phrase that was used in it. This
6 way there is no -- I won't botch the sentence and
7 I will just show it to you. There is a sentence
8 right here on the third bullet point.

9 A. Okay. Yes, okay.

10 Q. If you could take a look at that, I will
11 pass it over to you.

12 A. Thank you.

13 Q. You can read that.

14 A. The use of opiate analgesics by
15 physicians for the treatment of patients with
16 acute or chronic pain remains inadequate at best,
17 yes.

18 Q. And, you believe that is true even as of
19 today?

20 A. I do, yes.

21 Q. So, I am going to rephrase it a little
22 bit differently but I think it is the same
23 question. So it is your belief that the use of
24 opioid analgesics such as OxyContin by physicians
25 for the treatment of patients with acute pain is

1 inadequate at best?

2 A. Well, I would drop out OxyContin because
3 in acute -- OxyContin is not a drug that is
4 commonly used for acute pain.

5 Q. Do you believe OxyContin is appropriate
6 for use by physicians for patients with acute
7 pain?

8 A. The indications are for patients who
9 have pain that is going to last more than several
10 days and that requires continuous dosing and
11 acute pain may not require that.

12 Q. Well, in fact, it says extended period
13 of time, I think now, doesn't it? Do you know
14 what the package insert says for OxyContin?

15 A. I don't know, I would have to look at
16 it.

17 Q. OxyContin when it was first promoted,
18 first came out, as I understand it, had in the
19 package insert, the indication of pain lasting
20 more than a few days. Do you recall that at all?

21 A. I have heard that, yes.

22 Q. Do you know whether that has been
23 changed?

24 A. I think it was changed to be for
25 continuous use of a controlled release, need for

1 continuous administration but I would need to
2 look at it.

3 Q. If I were to say to you --

4 A. To be fair to you, I would need to look
5 at it.

6 Q. If I were to say to you that the
7 indication for a drug was that the pain had to be
8 for an extended period of time, what would that
9 mean to you, an extended period of time?

10 A. More than -- several days or more.

11 Q. Would you associate that more with
12 chronic pain than acute?

13 A. I would.

14 Q. The phraseology, extended period of
15 time, you would associate more with chronic pain
16 than acute pain; is that right?

17 A. That is correct. However, there are
18 patients that have -- this gets into the
19 definition. If you say chronic pain is greater
20 than three months, then there are patients with
21 acute pain that have it for three months, and
22 OxyContin would be appropriate if a patient was
23 requiring medication for three months. So again
24 it depends on the definition of acute and chronic
25 pain.

1 Q. A lot of definitions?

2 A. Yeah. No, it does.

3 Q. And, the next thing here, we talked
4 about this already, there is confusion among
5 physicians and patients about what is meant by
6 physical dependence and addiction in that you
7 believe it attributes or causes some fear among
8 people --

9 A. Yes.

10 Q. -- for using opioid drugs; right?

11 A. Yeah, um-uh.

12 Q. Now, physical dependence, is it your
13 belief that something happens physiologically to
14 the body to cause the body to need and become
15 physically dependent on the drug?

16 MR. HOFFMANN: I object to the form of
17 the question, you may answer it.

18 BY MR. COLANTONIO:

19 Q. Do you understand my question?

20 A. It's not a matter of opinion. There are
21 a variety of scientific studies that it
22 demonstrated that exposure of receptors to
23 opioids lead to changes in their cyclic AMP which
24 lead them to then cause a variety of effects when
25 the drug is withdrawn.

1 Q. So, when I take the drug, if I develop
2 physical dependence, then something happens
3 chemically to my body that makes my --

4 A. Well --

5 Q. Sorry.

6 MR. HOFFMANN: Go ahead and finish your
7 question.

8 MR. COLANTONIO: Thank you.

9 MR. HOFFMANN: I was cautioning her not
10 to answer your question before you finish it.

11 MR. COLANTONIO: I probably lost my
12 train of thought.

13 MR. HOFFMANN: I am sorry, maybe I
14 should just sit on my hands, but --

15 MR. COLANTONIO: I don't want you to sit
16 on your hands.

17 THE WITNESS: Sorry.

18 BY MR. COLANTONIO:

19 Q. It's your belief that the person who
20 becomes physically dependent, takes a drug, there
21 are physiological changes to their body that make
22 it such that if the drug is withdrawn that the
23 body will react adversely or in a way that comes
24 about because of these physiological changes?

25 A. Yes.

1 Q. Now, do you believe that there are
2 physiological changes that happen to the body
3 upon ingestion of a drug that are a contributing
4 factor to the development of psychological
5 dependence or addiction?

6 A. There is no clear correlation between
7 physical dependence and addiction.

8 Q. Is what you mean by that that people who
9 are physically dependent, just because they are
10 physically dependent does not mean they are
11 addicted?

12 A. That is correct.

13 Q. But, my question is a little bit
14 different, I think, and that is do you believe
15 that in terms of psychological dependence or
16 addiction, that there is something, that there is
17 a physiological mechanism to that, to addiction
18 and psychological dependence?

19 A. The evidence would suggest that there
20 are a series of neuro pharmacologic changes that
21 occur within the brain with exposure to opioids
22 that are associated with psychological
23 dependence.

24 Q. So, that would also, I think, mean that
25 in terms of psychological dependence and

1 addiction, there are something physiological
2 going on that --

3 A. I am attempting to be specific by
4 calling them neuro pharmacologic because they
5 happen in the brain predominantly.

6 Q. A person who has addiction can have
7 physical dependence as well; is that right?

8 A. Can you say that again?

9 Q. A person who has psychological
10 dependence or addiction to opioids can also have
11 physical dependence, right?

12 A. Yes, correct.

13 Q. A person who abuses opioid medication,
14 prescription or otherwise, that can be an
15 indication of potential addiction; is that true?

16 A. Potential, yes.

17 Q. And, in terms of differentiating whether
18 somebody has true physical dependence, true
19 psychological dependence or addiction or just
20 drug abuse problems, would you agree that to sort
21 those things out, that one should evaluate the
22 patient and try to figure out which one or a
23 combination of those might be at issue in a
24 patient?

25 A. That is correct.

1 Q. Would you expect to see a higher rate of
2 addiction in a pool of patients that have both
3 higher dose of opioids such as OxyContin and
4 longer use of the drug?

5 A. You know, I think that's the million
6 dollar question. We don't know the answer to
7 that.

8 Q. Would you expect to see a higher rate of
9 addiction in a pool of patients who have certain,
10 a certain subset of socioeconomic psychological
11 factors than another subset?

12 A. Again, that's been looked at and not
13 clearly well defined. I think that one of the
14 important issues in all of this is that merely
15 exposure to opioids does not produce addiction.
16 And so trying to sort out what those factors are
17 is the -- is an important aspect.

18 There is evidence to suggest that
19 patients who have a history of alcohol abuse or
20 have a history of drug abuse may be at greater
21 risk. But, these are very limited information.

22 Q. That's the \$2,000,000 question?

23 A. Yeah.

24 Q. All right; in terms of history of
25 alcohol abuse, let's say that you have a patient,

1 comes into your offices, and they want to -- you
2 are considering OxyContin as a potential drug,
3 and you take a history of a patient. If a
4 patient had gotten drunk socially, let's say, I
5 don't know, once every three weeks or something
6 like that in the past year, would you consider
7 that a history of alcohol abuse?

8 A. There are different criteria that you
9 can use to assess a patient. And, you know, this
10 has been well described as to whether they binge
11 or whether they take five drinks a week,
12 etcetera. So there is an assessment that one can
13 do of a patient. But there are a couple of
14 studies out there that begin to look at this.

15 Nat Katz looked at a group of patients
16 with chronic opioid therapy and demonstrated that
17 those patients that had a history of alcohol
18 abuse did fine in his clinic and did not develop
19 any risk of addiction. And, Edwardo Bruera in a
20 large population of cancer patients used alcohol
21 abuse as one of the factors that you might
22 evaluate the success of pain treatment in a
23 cancer population and he eventually threw out
24 alcohol abuse because it became a variable that
25 wasn't helpful.

1 Q. But this Katz and is it Bruera, are they
2 recent studies or --

3 A. Katz is a recent study. It's a really
4 nice piece and I can get you the reference. I
5 don't have it with me, but it's really -- I
6 forget who wrote it with him, but it's a nice
7 piece.

8 Q. Now, we're going to get into definitions
9 again. What is recent?

10 A. In my world, recent is like the last
11 three years or four years. And Edwardo, I would
12 have to see where he published that but the Katz
13 papers were recently published.

14 Q. Now, let's talk about history of drug
15 abuse.

16 A. Yes.

17 Q. If somebody had smoked, let's say,
18 marijuana in college or something like that,
19 would you consider that a history of drug abuse
20 in your evaluation?

21 A. Yeah. It would be written down as a
22 history of drug abuse, yeah.

23 Q. And, would you think that kind of a
24 person would be -- fall into that category of
25 maybe the higher risk of potential addiction to

1 some others?

2 A. I don't think we have any information on
3 that.

4 Q. That falls into the paucity of data --

5 A. That alone, you know.

6 Q. That would fall into the paucity of data
7 column?

8 A. You know, I don't think I know the
9 answer to that because I don't -- there may be
10 research that has looked at marijuana and its
11 implications, I just don't know it.

12 Q. Do you in your own practice consider a
13 history of drug abuse like somebody who smoked
14 marijuana in their past or maybe abused a drug,
15 prescription medication, took it more than was
16 prescribed, do you consider that an additional
17 risk factor for development of addiction when you
18 are considering prescribing an opiate?

19 A. I consider it as an important piece of
20 information. And, you know, again, I don't want
21 to discriminate against the patient who may in
22 the past have misused drugs. And so in that
23 setting, it's a piece of information that you
24 want to have information about the patient on and
25 information to what the causes of why they did

1 it, how they did it, whether they continued to do
2 it, what they think about it. And also the very
3 fact that the patient is open and willing to tell
4 you that in an interview suggests that it may not
5 be at all an issue.

6 And, when you have to weigh the risks
7 and benefits of treating a patient, it is a
8 dilemma that you face, a very real dilemma. So,
9 yes, it's a piece of the history that you put,
10 it's the piece that you pay attention to and in
11 that patient, it might represent a greater
12 concern or a red flag.

13 Q. It could be something that would make
14 you consider not prescribing OxyContin for
15 somebody, depending on how you felt about it;
16 correct?

17 A. Well, I think, again, I don't -- it
18 could make some people make that decision. But I
19 would hope that they had more information and
20 weighed the benefits to the patient of treating
21 their pain than the risk of the drug.

22 Q. That's pretty much true every time a
23 physician writes a prescription, that's kind of a
24 risk benefit, you want to make sure that the drug
25 is not going to cause more damage than --

1 A. More harm to the patient.

2 Q. In fact, that's kind of the concept of
3 physician practice, don't cause harm and don't --
4 isn't that true?

5 A. Yes, it would be that.

6 Q. Do no harm, I think I have heard that
7 before?

8 A. But, I think particularly when you see a
9 patient writhing in pain who is profoundly
10 suffering, that is rather compelling than simply
11 looking at a blood pressure number or looking at
12 a cholesterol level, it's quite profound.

13 Q. Especially in cancer pain patients?

14 A. No, I think it's even sadder in patients
15 that don't have cancer because they may not die
16 and they may have to live with it.

17 Q. If a patient has terminated opioid
18 medication and they have developed addiction,
19 there could be a reason for continued management
20 of that patient, is that correct?

21 A. Well, could you say that again?

22 Q. Sure. If a patient has stopped opioid
23 medication but the patient has developed
24 psychological dependence or addiction, there
25 could be a potential reason to continue to treat

1 that patient?

2 MR. HOFFMANN: I am going to object to
3 the form of the question but you may answer
4 if you can.

5 BY MR. COLANTONIO:

6 Q. Due to the risk associated with
7 addiction --

8 MR. HOFFMANN: I still object to the
9 form of the question.

10 THE WITNESS: Well, if a patient is an
11 addict, they are an addict and they are
12 abusing the drug. If a patient has a history
13 of drug addiction, they don't need treatment
14 so I don't --

15 BY MR. COLANTONIO:

16 Q. Well, I think you indicated before that
17 if a patient does develop addiction, they could
18 need treatment to treat that condition,
19 addiction, correct?

20 A. I did and that would be a patient who
21 has, let's say, actively been misusing opioids,
22 is physically dependent on them so they need the
23 opportunity to be detoxified from their drug.
24 They need to be put into any one of a series of
25 programs like a drug abstinence program, a drug

1 free program, a narcotics anonymous program, a
2 methadone maintenance program or buprenorphine
3 program, okay, for a period of time.

4 But once they have done that and once
5 they are no longer on the opioids and once they
6 are discharged from those programs which lasts
7 periods of time, they don't need to -- they don't
8 need more treatment.

9 Q. Don't those programs also often times
10 have periods where patients come back? There can
11 be relapses, there can be additional support
12 provided for the person to deal with this
13 lifelong problem?

14 A. Well, if the patient has a relapse, then
15 they need treatment for the relapse. But they
16 don't -- if they don't have a relapse, they don't
17 -- they don't have anything they need a treatment
18 for.

19 MR. COLANTONIO: Let's take five
20 minutes.

21 THE VIDEOGRAPHER: Going off the record,
22 10:46.

23 (Whereupon, a brief recess was taken.)

24 THE VIDEOGRAPHER: Returning to the
25 record 11:04.

1 BY MR. COLANTONIO:

2 Q. Do you agree with this statement, drug
3 addiction is a treatable disease utilizing a
4 multi disciplinary approach but relapse is
5 common?

6 A. Yeah.

7 MR. COLANTONIO: Those are all the
8 questions I have.

9 MR. HOFFMANN: Why don't we see if the
10 people on the phone have questions.

11 MS. SEAMON: I don't have any.

12 MR. FARRELL: Bob Farrell, I have none.

13 MS. DOBBINS: This is Stephanie Dobbins,
14 I have no questions.

15 MR. HOFFMANN: It is our hope that
16 Dr. Foley will testify live. But in case
17 that turns out not to be possible, I am going
18 to ask some questions on direct.

19 MS. LYONS: Are you going to be doing
20 that from there, Bill?

21 MR. HOFFMANN: No, I was going to
22 suggest that I switch seats so that she is
23 looking into the camera when she is
24 responding to me.

25 THE VIDEOGRAPHER: Going off the record,

1 11:05.

2 DIRECT EXAMINATION

3 BY MR. HOFFMANN:

4 Q. Dr. Foley, I just have a few questions
5 for you. First, when did you receive your
6 medical degree?

7 A. In 1969.

8 THE VIDEOGRAPHER: Returning to the
9 record, it's 11:09, beginning of tape number
10 three.

11 MR. HOFFMANN: I'm sorry, I beg your
12 pardon.

13 BY MR. HOFFMANN:

14 Q. Dr. Foley, when did you receive your
15 medical degree?

16 A. 1969.

17 Q. And, do you hold any board
18 certifications?

19 A. I am board certified in neurology and
20 psychiatry.

21 Q. And, when did you become board certified
22 in neurology and psychiatry?

23 A. 1975.

24 Q. How would you describe your specialty in
25 the field of medicine?

1 A. I was trained as a neurologist and then
2 as a neuro oncologist and then as a clinical
3 pharmacologist. And I work at Memorial Sloane-
4 Kettering Cancer Center and my focus has been on
5 the clinical pharmacology of opiate analgesics in
6 patients with pain.

7 Q. How long have you been focusing on the
8 clinical pharmacology of opioid analgesics in the
9 treatment of pain?

10 A. Really, since I finished my residency
11 since 1974, when I went to Memorial.

12 Q. Have you prescribed opioids to patients
13 since 1974?

14 A. Yes, I have and before that as well as
15 an intern and resident.

16 Q. And, over the course of your practice,
17 can you give me any kind of estimate as to how
18 many patients you have prescribed opioids to?

19 A. Thousands of patients.

20 Q. And, do you continue prescribing opioids
21 to patients today?

22 A. Yes.

23 Q. Have you -- in prescribing opioids to
24 patients, do you see any advantages to long
25 acting or sustained released opioids compared

1 to on the one hand, compared to short acting or
2 immediate release opioids on the other hand?

3 A. Well, for patient's convenience, it has
4 had a very important impact because instead of
5 having to take a medication every three hours or
6 four hours, they can take it every eight hours or
7 12 hours or in some cases every 24 hours because
8 there is a series of preparations out there that
9 allow them that kind of variability.

10 Q. Did you have anything to do with the
11 development of sustained release opioids?

12 A. In the late seventies and early
13 eighties, there was an increase in attention to
14 the role of oral morphine in patients with pain
15 and cancer. And after there was available oral
16 morphine in an immediate release, there was an
17 increasing interest by a variety of companies to
18 develop slow release or controlled release
19 preparations. And so we worked with a variety of
20 companies in developing slow release and
21 controlled release preparations for Morphine.

22 Q. When you say we worked with a variety of
23 companies, just what did you do?

24 A. My particular role was in advising the
25 companies about who had cancer pain, who would be

1 appropriate for studies, what the study designs
2 might be, those particular aspects.

3 Q. Did you have anything to do with the
4 encouragement of the pharmaceutical industry to
5 develop a sustained release morphine?

6 A. Yes, because we felt that patients would
7 benefit from drugs that would facilitate their
8 ability to have continuous pain relief. So, we
9 were encouraging to the pharmaceutical companies
10 I guess would be the best.

11 Q. Now, I want to understand a little bit
12 about your patients because, as I understand it,
13 you work at a facility that specializes in the
14 treatment of cancer. Would it be fair for us to
15 assume that all the patients you treat have pain
16 from cancer and will be on opioids until they die
17 from that cancer pain?

18 A. No. Again, when we started, since we
19 were clearly -- the clinic was called the Medical
20 Pain Clinic. It was initially developed by Gray
21 Hood and it became -- in it we saw a wide variety
22 of patients with both cancer pain and non-cancer
23 pain.

24 Q. Have you in your professional experience
25 ever prescribed opioids to patients for pain and

1 then had that pain, the pain -- the cause of the
2 pain resolve and you wean the patients off of
3 opioids?

4 A. In our setting, it has been a very
5 common phenomenon to see that, both in the group
6 of patients who have prolonged post surgical pain
7 syndromes that last weeks or months, patients who
8 have prolonged orthopedic procedures and patients
9 who have, for example, neurologic pain syndromes
10 like brachial avulsions of the brachial plexus or
11 have post -- acute herpes zoster that then goes
12 on to post herpetic neuralgia. And there are
13 groups of patients who for a period of time take
14 opioids and then are tapered off the drug because
15 they are rehabilitated, they are improved, their
16 pain dissipates and they are no longer taking
17 them.

18 Q. I asked you about patients that you had
19 prescribed opioids to but are you also familiar
20 with patients that fellows in your program
21 provide opioids to?

22 A. Since 1975, we have had a training
23 program and, you know, Dr. Portenoy, Dr. Paine, a
24 whole variety of individuals who now are experts
25 in this area have trained in our program.

1 Q. Now, of the patients that you are
2 familiar with through your treating them
3 personally and supervising your fellows in
4 treating them, what percentage of patients do you
5 find are successfully weaned off of opioids when
6 their pain issue resolves and then subsequently
7 become opioid addicts?

8 MR. COLANTONIO: I am just going to
9 object to the form of the question and also
10 object on lack of foundation.

11 BY MR. HOFFMANN:

12 Q. Doctor, go ahead and answer it.

13 A. Could you repeat the question?

14 Q. Yes. Of the patients to whom you
15 prescribe opioids and to whom your fellows
16 prescribe opioids, what has been your experience
17 in terms of patients who have been prescribed
18 opioids, then weaned off of the opioids when
19 their pain issue resolves and then at some
20 subsequent time become opioid addicts?

21 MR. COLANTONIO: Same objection.

22 THE WITNESS: That has not been part of
23 our experience. We haven't seen that occur
24 in our patients. The patients have been
25 tapered off their drug successfully and

1 unless they have a recurring pain problem
2 which they may go back on their drug, that
3 may occur, but we haven't seen them develop
4 any problems with just having been exposed to
5 the drug as part of a surgical procedure or
6 prolonged post surgical procedure or as part
7 of any other cancer illness or non-cancer
8 illness.

9 BY MR. HOFFMANN:

10 Q. Well, would you know if they did?

11 A. Well, again, because these patients
12 often are in a setting of a cancer institution,
13 we would see them because they may come back to
14 our institution if they had a relapse and might
15 have abhorrent behaviors. They would typically
16 come back to us because, and we would know about
17 them because the physicians who may be treating
18 them would want their records for what had
19 happened to them in the past. And those records
20 requests would come directly to our program. So,
21 we would tend to have a sense of who they were.

22 MR. HOFFMANN: I want to mark this as an
23 exhibit.

24 (Whereupon, Defendant's Exhibit 1 was
25 marked for identification.)

1 BY MR. HOFFMANN:

2 Q. Dr. Foley, we have handed you what has
3 been marked as Defendant's Exhibit No. 1 and I
4 will represent to you that that is an exhibit to
5 the deposition of Edon Nelson that has been taken
6 in this case. Is that a document that you have
7 reviewed previously?

8 A. Yes, I think I have.

9 Q. I want to ask you a few questions about
10 that. Specifically looking at paragraph one and
11 the last sentence of paragraph one, it states,
12 however, it is standard medical practice to avoid
13 the use of opioids for persons suffering long
14 term non-traumatic moderate levels of pain
15 because continued pain management can only be
16 achieved over time by increasing the dose of the
17 opioid prescribed. Do you agree with that
18 statement, Dr. Foley?

19 A. No, I don't agree with that statement.

20 Q. Why not?

21 A. Well, again, it would be helpful to take
22 it in different pieces or parts. First of all,
23 now, it's been recognized that there are -- there
24 is a sub group of patients who may respond
25 effectively to opioid analgesics on a chronic

1 long term basis and they would be potential
2 candidates. And, again, there have been a
3 variety of studies that have demonstrated the
4 efficacy of opioid analgesics in patients with
5 neuropathic pain and different types of arthritis
6 pain and in patients with low back pain and
7 patients with post herpetic neuralgia and
8 patients with peripheral neuropathy. So there
9 have been now guidelines written by the American
10 Pain Society and the Academy of Pain Medicine to
11 identify that such patients may benefit and
12 should be considered for treatment. So, that's
13 my sort of first part.

14 I disagree with that the construct that
15 continued pain management can only be achieved
16 over time by increasing the dose of opioids
17 prescribed and I disagree with that statement
18 because even our very small study of the 38
19 patients that we talked about previously
20 demonstrated that those patients did not
21 necessarily escalate their drug.

22 And, again, there is increasing evidence
23 that patients can stay stable for long periods of
24 time on chronic opioid therapy.

25 Q. Let me ask you a little bit more about

1 that because it is my understanding that
2 Dr. Nelson has opined that because of the
3 development of tolerance, there is no plateau
4 that patients reach and a patient prescribing
5 opioids will continue to need escalating doses of
6 opioids as the tolerance to the opioid
7 increases. Has that been true in your
8 experience?

9 A. It's not been true in our experience or
10 in others in which this conceptualization of
11 tolerance which does develop in some patients,
12 the development of tolerance per se has been
13 hypothesized to be the driving force for why
14 patients require higher doses of drugs. And yet
15 when one looks at it in a population of patients,
16 one sees that it's typically the change in the
17 pain stimulus that is driving the requirement for
18 an increase in the drug.

19 And so the animal studies that are the
20 basis for this whole understanding of this
21 phenomenon were done in which the stimulus was
22 kept the same. When you change the stimulus as
23 occurred in patients, the reason for them
24 increasing their dose of drug is then escalating
25 pain or progression of disease.

1 So, the bottom line to all of this is
2 that tolerance occurs to different effects of the
3 drug at different rates, that many patients can
4 take a stable dose of drug for a long period of
5 time and there is literature to support that and
6 so that they don't just increase their drug
7 continuously but rather stay at a stable dose.

8 Q. Can you recall any examples of patients
9 that you have had that have been on a continuing
10 non-escalating dose of a particular opioid for
11 over a year, for example?

12 A. I mean, I have a series of patients like
13 that. I have a woman who is an 85 year old
14 patient who takes oxycodone and has been taking
15 exactly the same dose for relatively -- has been
16 taking -- she has been taking 240 milligrams of
17 oxycodone for now five or six years for
18 neuropathic pain syndromes. And she lives
19 independently and lives here in the city and her
20 daughter lives in the same building. And I see
21 her on a regular basis and she has not escalated
22 her dose of drug, as an example.

23 Q. Has this impaired her cognitive
24 function?

25 A. No, she is fully independent, has been

1 able to live independently.

2 Q. In your experience, does being on a
3 continuous high dose of opioids such as you
4 described for this patient, impair a person's
5 cognitive functioning?

6 A. It potentially could but our experience,
7 again, is that patients become quite tolerant to
8 the side effects that impair cognitive function
9 so that they are tolerant to the sedative effects
10 and they are tolerant to the somnolent effects
11 and they are tolerant to the confusion effects of
12 the drug so they remain stable.

13 Q. And, you mentioned with regard to this
14 patient that she was on oxycodone, any particular
15 -- well, was this particular patient on
16 OxyContin?

17 A. She was not on OxyContin because her
18 insurance company refused to pay for OxyContin.

19 Q. Do you prescribe OxyContin to some of
20 your patients?

21 A. Yes, I do.

22 Q. I would like you to look now at
23 paragraph three of Defendant's Exhibit 1 where it
24 states that it is a well established medical fact
25 that seven percent of all persons chronically

1 exposed to opioid analgesics will become addicted
2 to the narcotic. Do you agree with that?

3 A. No, I don't.

4 Q. Do you know -- do you as part of your
5 practice keep up with the literature on opioid
6 addiction?

7 A. Yes, I do.

8 Q. Are you aware of any support in the
9 literature on opioid addiction that would support
10 that statement in paragraph three?

11 A. I don't know of any data that would
12 support that. I mean, all the data that I know
13 of says that we don't know this number.

14 Q. What if we change that number to three
15 and a half percent, what would your answer be
16 then?

17 A. I would still say that we don't know the
18 number.

19 Q. There is a statement in the package
20 insert that says in effect that addiction to
21 opioids when prescribed for pain is rare. Do you
22 agree with that or disagree with that?

23 A. Yes, I agree with that.

24 Q. What is the basis for your agreement
25 with that?

1 A. First of all, it is my only clinical
2 experience in treating patients with pain. And,
3 again, this has been the evolution of having the
4 opportunity to be able to provide chronic opioid
5 therapy for patients for years at a time and to
6 see how rare this phenomenon is in that patient
7 population. So, that's one basis. And,
8 increasingly, that of my colleagues who have also
9 observed this.

10 And then when Dave Durrenson looked at
11 the relationship between increasing prescriptions
12 of opioid analgesics and increasing the abuse
13 from like 1990 to 1996, he demonstrated that
14 there was no evidence of abuse. And this is
15 again looking at that same period.

16 So there is a series of suggestions that
17 have identified and an increasing number of
18 patients who are being treated with opioids that
19 have begin to question whether anyone in the
20 setting of receiving opioids in the setting of
21 pain becomes addicted. And it is really I think
22 such a critically important question because the
23 experience of caring for patients and treating
24 pain in a medical setting is just totally
25 different than what we see happens in addicts who

1 take this drug and misuse it.

2 Q. Let me ask you to turn over to paragraph
3 12 on page 4 of Defendant's Exhibit 1, if you
4 would, please? In looking at the first sentence
5 there, it states, the duration of analgesia from
6 OxyContin falls short of the 12 hours published
7 in the package insert. Do you agree or disagree
8 with that?

9 A. I haven't reviewed all of the
10 pharmacokinetic data so I don't think I could
11 even agree with that statement because I don't
12 know that that statement is true. So --

13 Q. In your experience as a treating
14 physician, has the duration of analgesia from
15 OxyContin fallen short of the 12 hours published
16 in the package insert?

17 A. Again, in treating patients, you have to
18 choose the appropriate dose. So, if you -- the
19 time action of a drug will be directly related to
20 the dose you give the patient. So, if you end up
21 under dosing the patient, then they may have
22 inadequate analgesia and look like the drug
23 doesn't work for 12 hours.

24 So, I have a lot of respect for how the
25 FDA reviews this pharmacokinetic data in deciding

1 whether a drug works for what period of time
2 because they are very very stringent about that.
3 So, my sense is that typically you have to give
4 the patient the appropriate dose.

5 Q. If a patient is on active opioid
6 therapy, is there any obligation on behalf of the
7 treating physician to monitor that patient to
8 determine if symptoms of addiction begin to
9 occur?

10 A. Yes, of course.

11 Q. If a patient has been on opioid therapy
12 and has successfully weaned off of the opioid, is
13 there any reason to continue to medically monitor
14 that patient for the rest of his or her life to
15 determine if that patient will become an opioid
16 addict?

17 A. I mean, there is no, no indication to do
18 that and there is a lot of clinical data to
19 suggest that we would not do that.

20 Q. Let me ask you now to turn to paragraph
21 13 beginning on page 4 and continuing on page 5
22 of this, the Exhibit 1, Defendant's Exhibit 1.
23 And it's fairly long so I am going to ask you
24 just to read that paragraph to yourself and then
25 I would like to ask you what you agree with and

1 disagree with in that paragraph?

2 A. So to start with reading paragraph 13?

3 Q. Yes, just read paragraph 13.

4 A. I don't agree with what it says.

5 Q. Well, why don't you go through the
6 paragraph and take it any way you want, sentence
7 by sentence, if you would prefer, and explain
8 why, tell us where you don't agree and why you
9 don't agree?

10 A. Well, patients have used OxyContin and
11 have then discontinued the OxyContin and then
12 their pain has improved. They no longer require
13 taking the drug. There would be no reason to
14 monitor them for anything other than general
15 medical care. So it would not seem to me that
16 you would monitor them for anything related to
17 OxyContin.

18 Then this issue, exposure to large dose,
19 i.e., more than 30 milligrams per day, I don't
20 know of any evidence that, first that someone
21 would call 30 milligrams large doses. Second of
22 all, that that dose would produce these
23 particular effects. It may have some effects
24 that would be the foundation for addiction.

25 30 milligrams per day at least in the

1 published studies and I think it's up to -- I am
2 not quite sure, it's up to 60 milligrams,
3 patients could be abruptly stopped from their
4 drug and not even go into withdrawal. And this
5 was noted in a chronic long term study that was
6 published in patients receiving opioids for
7 osteoarthritis. So we have evidence that even up
8 to 60 milligrams when a patient was stopped, they
9 didn't even show signs of physical dependence.

10 So I don't know the basis, any
11 scientific basis for that dose of 30 milligrams.
12 So, to suggest that all persons have been exposed
13 to sufficient doses for a sufficient time to
14 produce a basis for addiction, I don't know of
15 any understanding or any basis and it clearly is
16 not within my clinical experience.

17 Then this sentence, euphoria is
18 produced from relief of pain. Well, every bit of
19 data shows that euphoria occurs independent of an
20 analgesic effect if it occurs. And again in the
21 oxycodone, OxyContin studies, euphoria was
22 reported to occur in somewhere between one to
23 five percent of patients as a side effect. So a
24 very rare complication compared to the
25 complications, the side effects that we have

1 reported.

2 So this construct of euphoria having --
3 the idea that euphoria is related to pain is
4 incorrect, number one. And that it occurs as a
5 result of oxycodone is a rare phenomena.

6 Oxycodone is metabolized to oxymorphone
7 but the data demonstrates that there is the major
8 active ingredient is oxycodone in producing the
9 analgesic effects. Then this idea that it is
10 remembered and leads to a desire to repeat the
11 drug administration, well, it is not even
12 remembered enough to produce physical dependence
13 which is often closely associated with drug
14 addiction.

15 So, it would seem to me unlikely that
16 there would be any clear relationship there. I
17 agree with the statement that intense drug
18 craving is a hallmark of opioid addiction.

19 So, in short, I don't know of any
20 evidence to suggest that if somebody has been
21 exposed to 30 milligrams of oxycodone that they
22 should be followed -- OxyContin, that they should
23 be followed for the rest of their life. And
24 there are a lot of patients in a post operative
25 setting who receive oxycodone which is the active

1 ingredient of OxyContin who sure are not being
2 followed for the rest of their life and have no
3 problems with addiction. So I don't think there
4 is a basis scientifically or in clinical
5 practice.

6 Q. You were asked some questions about your
7 CV or articles in your CV earlier this morning
8 and just for the record, I would like to mark and
9 include as an exhibit the CV that you were asked
10 about.

11 And let me just ask you, it appears that
12 the most recent publication on this, if these are
13 in fact in chronological order, is 2001 --

14 A. Yeah, that's wrong.

15 Q. And, we can substitute another CV at a
16 later date. But my question is, as of August,
17 2001, is this an accurate curriculum vitae for
18 you?

19 A. Do you want me to look at every page?

20 Q. No, just see if you recognize it as your
21 CV.

22 A. I do recognize it as my CV but we keep
23 addressing -- it may not be fully updated.

24 MR. HOFFMANN: Okay; then let's mark it
25 as Defendant's Exhibit 2 and make it part of

1 the record, then?

2 (Whereupon, Defendant's Exhibit 2 was
3 marked for identification.)

4 THE WITNESS: Okay; and it clearly isn't
5 updated since it's 2001.

6 MR. HOFFMANN: Let's take a break for
7 just a minute of minutes.

8 THE VIDEOGRAPHER: Going off the record
9 11:36.

10 (Whereupon, a brief recess was taken.)

11 THE VIDEOGRAPHER: Returning to the
12 record 11:40.

13 BY MR. HOFFMANN:

14 Q. Dr. Foley, I just want to try to clarify
15 one more thing from your testimony this morning
16 and that is the distinction between a weak opioid
17 and I guess a strong opioid.

18 A. That is correct.

19 Q. And, in the case of some opioids, does
20 the distinction between strong and weak depend on
21 dose?

22 A. Yes and no, but in drugs that are pure
23 agonist like oxycodone it is an issue of dose.

24 Q. Okay, well, let's stick with oxycodone.
25 Is it a hard and fast distinction or is it a

1 continuum between strong and weak.

2 A. It's been traditionally a way in which
3 drugs as they came on the market from about the
4 1950s on were categorized as to what was thought
5 to be their spectrum for analgesia. So, let's
6 say codeine has been considered sort of the
7 prototypic drug so doses of 30 or 60 milligrams of
8 codeine were identified as weak opioids and then
9 were studied in patients with mild to moderate
10 pain.

11 Q. Is OxyContin identified generally as a
12 weak opioid or a strong opioid?

13 A. Well, I think -- OxyContin, it is a
14 brand name. The agent is oxycodone and so I
15 think we just have to talk about oxycodone. And
16 oxycodone at low dose like five milligrams, ten
17 milligrams is considered a weak opioid. And
18 because of that consideration is why it was
19 placed in the WHO step two analgesic ladder at
20 step two and then it was placed in step three at
21 higher doses.

22 Q. And, is there a hard and fast line where
23 you draw the distinction between higher doses and
24 lower doses when you are talking about oxycodone?

25 A. Again, it's not a hard and fast line but

1 it's clearly doses of five milligrams or ten
2 milligrams have been considered low dose and at a
3 step two ladder.

4 Q. And, doses above that have been
5 considered strong opioids?

6 A. No, I am identifying those for sure and
7 above that again is quite individual. So, to be
8 fair -- and I think I would have to go back and
9 look this up -- but I think it would go up to
10 about 30 milligrams would consider it still in a
11 weak opioid class.

12 Q. 30 milligrams daily?

13 A. Yes.

14 MR. HOFFMANN: Those are all my
15 questions, thank you very much.

16 Now, Mr. Colantonio may have some
17 more or may not.

18 MR. COLANTONIO: I do have a few
19 questions, doctor.

20 REDIRECT EXAMINATION

21 BY MR. COLANTONIO:

22 Q. Doctor, in terms of the dosing of
23 OxyContin at Q 12 and the issue of the efficacy
24 of OxyContin over Q 12 over versus Q eight, are
25 you aware of any statistics that would indicate

1 the number of physicians who prescribe OxyContin
2 who actually write it at Q 8 versus Q 12?

3 A. I think in one of the many depositions
4 that I read, I read that there was IMS data that
5 suggested that some percentage, 14 percent or
6 something like that, I really would need to look
7 at exactly what they said, wrote the drug Q eight
8 hours.

9 Q. And, would you consider, if that's true,
10 12 to 14 percent of physicians write OxyContin at
11 Q eight and not Q 12, would you consider that
12 statistically a significant number of
13 physicians?

14 MR. HOFFMANN: I object to the form of
15 the question.

16 BY MR. COLANTONIO:

17 Q. Do you understand what that means?

18 A. I don't understand what that means.

19 Q. Do you understand what the term
20 statistically significant means?

21 A. As compared to what?

22 Q. As compared to -- in your profession, do
23 you understand what the term statistically
24 significant means?

25 A. Well, I would have to have all the data

1 to make that -- I don't know what the P value is
2 so what P value are we talking about.

3 Q. What do you mean by P value?

4 A. That's the degree of significance. So
5 you would have to have all the data to call that
6 significant.

7 Q. So, if you're trying to assess how many
8 physicians write a drug at Q 8 versus Q 12 and
9 you find out that 12 to 14 percent do that, would
10 you consider that a significant number of
11 physicians?

12 A. I would consider that a relatively small
13 number.

14 Q. Do you know the reason why physicians
15 would write OxyContin at Q eight versus Q 12?
16 Have you ever researched that at all?

17 A. No, and even if they write it, it
18 doesn't mean that that's how the patient takes
19 it.

20 Q. Well, we hope that a patient takes it
21 how we write it, isn't that right?

22 A. But writing it doesn't mean that's how
23 the patient is taking it.

24 Q. Are you aware of any information
25 indicating that patients had related to their

1 doctors that OxyContin after Q 8 was not working?

2 A. Um-uh.

3 Q. Versus Q 12?

4 A. Yeah, and I think this may be an example
5 of under treated pain of an inadequate initial
6 dose. And so one of the choices would be that
7 you would go up on the dose, you would increase
8 the dose and then expand the time interval. And,
9 we know when you study -- well, there are sort of
10 several aspects of this.

11 Some patients find that taking a drug on
12 a Q 8 hour basis provides them with adequate
13 analgesia and less side effects. So, they take
14 let's say they take 40 milligrams of OxyContin in
15 the morning and they can get relief for 12
16 hours. But they notice that for the first three
17 hours they are a litter bit more sleepy than they
18 would like to be and then they are fine.

19 But if they take 20 milligrams every
20 eight hours, they don't feel so sleepy in those
21 first three hours and their side effects spectrum
22 is less. And so it is more acceptable to them to
23 function at the way that they need to function to
24 take it on a Q eight hour basis. And this
25 reflects the individual variations of patients as

1 they take drugs.

2 And we have learned this with
3 transdermal fentanyl, we have learned this with
4 slow release morphine preparations, that you may
5 have to adjust it for some patients, the time
6 frame of using controlled release preparation
7 because it is the best way to minimize their side
8 effects.

9 So, there is a need to be that type of
10 flexibility and to prescribe that for some
11 patients.

12 Q. If you were to learn that a significant
13 number of patients reported that OxyContin was
14 not working for them relieving their pain beyond
15 Q eight, would that be a potential indication for
16 you that OxyContin was not being effective after
17 Q eight?

18 A. It's very possible but not being
19 effective would not be the information I would
20 need. I would need a lot more. I would need to
21 know what their side effects were. I would need
22 their dose. I would need to know whether their
23 dose was matched to their prior narcotic
24 exposure. So you would need to know all of those
25 pieces. But, in my experience, we often have to

1 change the interval on how we manage the
2 patient's pain based on the individual needs of
3 the patient.

4 And we have done pharmacokinetic studies
5 with all of these drugs which show some patients
6 half-life is four hours and some patients is
7 eight hours and some is 12 hours. So I would
8 have to know the half-life of the drug in that
9 particular patient.

10 Q. It would be a piece of the information
11 you would consider in terms of determining
12 whether or not the drug is effective?

13 A. If the patient has reported that, sure.

14 Q. As far as you were commenting on
15 Dr. Nelson's opinions and one related to
16 tolerance --

17 A. Yes.

18 Q. You agree that tolerance is a
19 predictable pharmacologic effect of opioid
20 treatment?

21 A. I wish it were predictable, it is not
22 predictable.

23 Q. Let me, if I could, step down the table
24 a minute and I want to show you what was provided
25 to us as your opinions in this case and ask you

1 to look at the bullet point towards the bottom of
2 the page. And it says here tolerance and
3 physical dependence are predictable pharmacologic
4 effects seen in response to repeated
5 administration of an opioid in both man and
6 laboratory animals. Do you agree with that
7 statement?

8 A. Yes and no. I think -- I wish I could
9 predict it but I will say yes, fine, I will agree
10 with it.

11 Q. Do you want to change your answer, what
12 you said?

13 A. No, it's fine, I will agree with it.

14 Q. So, are you saying that the answer you
15 just gave me a minute ago was incorrect and now
16 it is yes?

17 A. No, the answer I gave before is that I
18 can't answer it with yes it is predictable, no it
19 is not predictable. It has a series of other
20 paragraphs that would go with it.

21 Q. Let me ask you this question. Is that
22 statement on that piece of paper correct or
23 incorrect?

24 A. It is correct.

25 Q. And, you do agree that tolerance can

1 develop in patients who are --

2 A. Absolutely.

3 Q. And, if tolerance develops, then there
4 is a need to increase the dosage?

5 A. Well, tolerance to what?

6 Q. Well, how do you define tolerance?

7 A. Well, tolerance develops to a wide range
8 of the side effects of the drug. And what again
9 we have observed is that, for example, patients
10 develop tolerance to the respiratory depressant
11 effects of the drug.

12 Q. I guess what I am referring to is
13 tolerance to the effect of the drug on pain?

14 A. So tolerance to analgesia.

15 Q. Yes.

16 A. So, if a patient has tolerance to
17 analgesia, one would have to increase the dose.

18 Q. And, tolerance to analgesia is something
19 that occurs to patients on opioid medication like
20 OxyContin; is that true?

21 A. That's true.

22 Q. Now, you did indicate that you believed
23 that psychological dependence or addiction to
24 opioids is rare; is that your feeling?

25 A. That is correct -- is rare in patients

1 who are medically treated with opioids in the
2 setting of having a chronic pain syndrome.

3 Q. Do you believe that that
4 characterization rare is dependent upon, could be
5 dependent upon some of the factors we talked
6 about before such as the socioeconomic factors,
7 psychological factors, that it may be for a
8 particular sub group that the potential for
9 psychological dependence or addiction could be
10 greater than rare depending on those factors?

11 A. Yeah. Yeah.

12 Q. You also indicated that part of your
13 opinion is based on your own clinical experience
14 and then you mentioned you have treated a number
15 of patients. But have you ever gone back and
16 actually precisely quantified the exact number of
17 patients that you have treated?

18 A. I mean, I could do that because we kept
19 records of all the patients we saw.

20 Q. I understand you can do it. I am just
21 asking you if you ever actually have ever done
22 that.

23 A. At the annual reports at the end of the
24 year we said how many patients we saw.

25 Q. As you sit here today, do you know how

1 many exactly you saw?

2 A. No, I don't think I could give you an
3 exact number.

4 Q. As far as the number of those patients
5 that were treated with mild opioids versus strong
6 opioids, I presume as you sit here today you
7 can't tell me that exact number?

8 A. No, but the predominant number of
9 patients would be treated with opioids.

10 Q. I think my question was strong opioids
11 versus weak opioids, could you tell me --

12 A. No, I could not tell you that today.

13 Q. And, would you agree that as of today,
14 you believe the data is not available to
15 establish a true incidence of addiction to
16 opioids. Do you agree with that statement?

17 A. I agree with it.

18 Q. I think you indicated that your belief
19 about the rarity of psychological dependence or
20 addiction is based upon some published studies;
21 is that true?

22 A. There are published studies.

23 Q. Well, is your belief -- is your
24 statement that you believe psychological
25 dependence or addiction to opioids is rare, is

1 that based in any way on a study?

2 A. It is based really quite profoundly on
3 my clinical experience and then it is supported
4 by these clinical studies.

5 Q. So, your opinion that you have that
6 addiction or psychological dependence to opioids
7 is rare is based upon your clinical experience;
8 is that true?

9 A. That's correct.

10 Q. It is not based upon or in forming that
11 opinion, you are not relying upon the published
12 studies concerning addiction rates and opioid
13 treatments; is that true?

14 A. That's true, simply for the fact that we
15 probably have one of the largest populations of
16 patients who have been treated with opioids in
17 the country so it's a pretty large population.

18 Q. Now, when you talk about your own
19 clinical experience, you do have patients as you
20 indicate that would come back to you for
21 treatment because they might have cancer disease
22 or some other disease that requires retreatment;
23 is that correct?

24 A. Retreatment for their pain.

25 Q. Yes?

1 A. Um-uh.

2 Q. Or some physical problem?

3 A. I guess I don't know what you are asking
4 me.

5 Q. You are saying that the reason why a
6 patient would come back to you is retreatment for
7 pain; is that right?

8 A. That is correct.

9 Q. And, that's one way you indicated that
10 you could gauge whether or not that person was
11 addicted or psychologically dependent upon the
12 drug because you had a chance to reexamine that
13 person in the future after they stopped their
14 medication?

15 A. I guess so. But the patient wasn't
16 addicted when they left us so -- and, I don't
17 have any evidence that when they are not addicted
18 when they left us, that they come back to us
19 addicted unless they are abusing drugs on the
20 street.

21 Q. Well, is it possible that a person could
22 have opioid medication, stop that opioid
23 medication and a physician based upon how that
24 occurred believed that the person is not addicted
25 and that person could actually be addicted and

1 later on manifest the signs of that addiction?

2 MR. HOFFMANN: I object to the form of
3 the question.

4 BY MR. COLANTONIO:

5 Q. Do you understand my question?

6 A. It's a little complicated.

7 Q. Is the question complicated or the
8 issue?

9 A. Well, the issue is complicated but the
10 question is a little complicated so if I could
11 take it in pieces, like the first --

12 Q. Let me try to rephrase it for you. Is
13 it possible that a person could be on opioid
14 treatment like OxyContin --

15 A. So it could be -- can I interrupt you?
16 Is this all right?

17 Q. We will set up the circumstances.

18 A. So, go ahead. The patient is receiving
19 pain therapy for their pain.

20 Q. Yes.

21 A. And is taking OxyContin.

22 Q. Yes, they are then weaned off
23 OxyContin.

24 A. So their pain goes away and they are
25 taken off the drug.

1 Q. Yes, and at that time you believe that
2 they are not addicted to the drug, at the time
3 that their medication is stopped?

4 A. They have no abuse behaviors, they have
5 no abhorrent behaviors, they have no signs of
6 physical dependence, they have no signs of
7 psychological dependence, they haven't been
8 selling their drugs, I have no evidence of any of
9 that behavior, okay.

10 Q. Or you have some evidence but not enough
11 to convince you?

12 A. Say I have no evidence.

13 Q. Say you have no evidence. Is it
14 possible that that person could still have
15 addiction but it doesn't manifest itself until
16 later on?

17 A. No.

18 Q. That is not a possibility?

19 A. Well, addiction -- if we agree with the
20 definition of what addiction is, they don't have
21 it. They don't have what is addiction.

22 Q. But, is it possible that -- I mean,
23 addiction is based on to a large extent what a
24 person does?

25 A. Right, they are not doing it so they

1 don't have it.

2 Q. Is it possible that they can do it later
3 on after they leave that treatment and they can
4 be addicted to the drug?

5 A. But, everything is possible, you know.

6 Q. I am just asking you if this is
7 possible.

8 A. No, I would say it's highly impossible
9 but who am I to say. But since everything in the
10 world is possible but then you wouldn't call them
11 addicted, it's -- it doesn't make sense.

12 Q. What would you call them?

13 A. Well, if they are addicted, then they
14 have all of the patterns of the behavior. I
15 don't know what to call them. I wouldn't even
16 ever think that this was an issue.

17 Q. So, to your way of thinking, a person,
18 if they stopped a medication and they don't have
19 the signs of addiction at that point, they can
20 never never be addicted to that drug?

21 A. Ever in the future?

22 MR. HOFFMANN: Object to the form of the
23 question.

24 MR. COLANTONIO: That's fine.

25 THE WITNESS: They could be addicted to

1 the drug if they took it another time and
2 something else happened, that could happen.
3 But pure exposure to the drug in the setting
4 of pain is not any reason to say that they
5 could be addicted.

6 BY MR. COLANTONIO:

7 Q. But, exposure is a prerequisite for
8 addiction; true?

9 A. You can't be addicted to the drug if you
10 don't take it. You can't be addicted at the time
11 if you haven't and are not taking it.

12 Q. So, you need exposure to the drug --

13 A. At the --

14 Q. I am sorry, to have addiction?

15 A. You need exposure to the drug at the
16 time that you are being called an addict.

17 Q. And, you agree that there is or physical
18 dependence is often associated with addiction; is
19 that true?

20 A. It is often associated but it is not
21 necessarily has to be part of the definition.

22 Q. But, it is often associated with
23 addiction; is that true?

24 A. It's associated.

25 Q. Now, as far as the WHO step two ladder

1 --

2 A. Yes.

3 Q. You indicated that that -- you said
4 something like that's why OxyContin is on step
5 two, I think. I just want to make sure I am
6 clear about this. You stated in testimony here
7 before we broke before that the WHO step ladder,
8 step one, is mild pain; true?

9 A. Yes.

10 Q. And, you stated --

11 A. Mild, yes.

12 Q. And, you stated that step two was
13 moderate pain; is that true?

14 A. Um-uh.

15 Q. You have to say yes.

16 A. Yes.

17 Q. And, step three is severe pain. True?

18 A. Right.

19 Q. It would be incorrect to suggest that
20 step two is mild pain; true?

21 A. No, I wouldn't say that because again as
22 it has been described, no one could tightly
23 categorize and just say mild pain and moderate
24 and severe. So, it was said mild to moderate,
25 moderate to severe. And so if you look at it,

1 it's this continuum and where does the end of
2 high mild pain enter into the early parts of
3 moderate pain. And that's the dilemma.

4 So the important aspect is that these
5 drugs were categorized. And that's why we went
6 even further to categorize them as weak opioids
7 versus strong opioids, to recognize that there is
8 this continuum and we can't say that the person
9 at the high end of mild pain reporting it at a
10 four and five isn't really moderate pain and the
11 person who reports a seven isn't severe pain.

12 So simply that language of mild,
13 moderate and severe is forcing us into a box that
14 is arbitrary.

15 Q. But, it is a step ladder and it does
16 have labeling to it?

17 A. It does have labeling to it, right.

18 Q. Is the labeling step one is mild, step
19 two is moderate, step three is severe or is it
20 that step two is mild to moderate and step three
21 is moderate to severe, which labeling is correct?

22 A. I think all of the labeling is correct
23 because it's a continuum. It's a continuum.

24 Q. So --

25 A. So that when we talk about mild,

1 moderate and severe, we are talking about
2 intensity of pain. When we talk about the drugs
3 used, okay, then we are talking about
4 non-opioids, weak opioids and strong opioids.
5 And the problem here is I think you are asking me
6 to compare apples and oranges.

7 Q. I don't want to ask you to compare
8 apples and oranges. I want to stick to oranges
9 and oranges.

10 A. Okay, me too.

11 Q. So, is it your testimony then that step
12 two includes mild pain?

13 A. It could include mild pain.

14 Q. OxyContin is not indicated for mild
15 pain; true?

16 A. Again, oxycodone.

17 Q. My question is OxyContin.

18 A. But, the WHO ladder never talks about
19 OxyContin, it only talks about oxycodone. It
20 never uses brand names.

21 Q. I accept that. I am just asking you a
22 question. If you know whether or not OxyContin,
23 the drug OxyContin --

24 A. It wouldn't, we don't include it in the
25 list because it is not a generic drug.

1 Oxycodone, we don't use any of those. We don't
2 use any label to a name and that's the name of a
3 drug. So I am going with oxycodone because
4 that's where the data is.

5 Q. Do you know whether OxyContin is
6 indicated for mild pain?

7 A. I think that it is not. I think it's
8 indicated for moderate to severe pain.

9 Q. In your clinical practice, do you know
10 how many patients had been prescribed OxyContin
11 versus other opioids?

12 A. In our clinical setting?

13 Q. In your clinical setting.

14 A. On an outpatient setting, oxycodone has
15 been a commonly used drug and then those patients
16 take OxyContin. I would have to look to tell you
17 the number. I don't think I know that offhand.

18 Q. And, certainly in 1985 -- you started
19 practicing medicine at Sloan-Kettering in what,
20 19 --

21 A. I was at Memorial appointed in 1974.

22 Q. And, so you had been practicing medicine
23 in cancer pain for some years before 1985; is
24 that correct?

25 A. From 1974 to 1985.

1 Q. And, you had a significant experience
2 with treating patients with cancer pain as of
3 1985; isn't that correct?

4 A. And non-malignant pain.

5 Q. And that was at the time you wrote the
6 articles we talked about earlier today; is that
7 correct?

8 A. That is correct.

9 MR. COLANTONIO: Those are all the
10 questions I have.

11 MR. HOFFMANN: I just have one question
12 and I am not going to move, if you could look
13 at the camera when you respond.

14 RECROSS EXAMINATION

15 BY MR. HOFFMANN:

16 Q. Your expert disclosure that
17 Mr. Colantonio talked about contains this
18 sentence. Tolerance varies enormously among
19 patients, do you agree with that?

20 A. Yes, I do.

21 Q. And, to the extent that there is
22 individual patient variation, is tolerance
23 predictable or unpredictable on a patient by
24 patient basis?

25 A. In the individual patient, the

1 development of tolerance is very unpredictable.

2 Q. But, if opioids are taken at a
3 sufficiently high dose in general, is it
4 predictable that some degree of tolerance will
5 occur?

6 A. Yes.

7 MR. HOFFMANN: That's all I have.

8 REDIRECT EXAMINATION

9 BY MR. COLANTONIO:

10 Q. Sufficiently high dose being more than
11 what, the 30 milligrams you talked about earlier,
12 a day?

13 A. Yes.

14 MR. COLANTONIO: Thank you. That's all
15 the questions I have.

16 THE VIDEOGRAPHER: Going off the record,
17 12:05 p.m.

18 MR. HOFFMANN: Unless anyone on the
19 phone wants to chime in.

20 (Whereupon, Ms. Lyons ordered a dirty
21 disc, regular copy and minuscrit expedited.
22 Mr. Hoffmann ordered a dirty disc only.
23 Mr. Colantonio ordered the transcript regular
24 delivery with a minuscrit and Mr. Farrell
25 ordered a minuscrit and ASKII.)

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C E R T I F I C A T E

I, Susan Wandzilak, Registered Professional Reporter and Notary Public in and for the State of Connecticut do hereby certify that the foregoing pages are a true and accurate transcription of my stenographic notes taken of these proceedings.

I further certify that I am not related nor in any way interested in the outcome of this case.

SUSAN WANDZILAK